



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,858	12/14/2004	Hassan Mohammad	222.1105	1242

23280 7590 03/04/2009
Davidson, Davidson & Kappel, LLC
485 7th Avenue
14th Floor
New York, NY 10018

EXAMINER

BARHAM, BETHANY P

ART UNIT	PAPER NUMBER
----------	--------------

1615

MAIL DATE	DELIVERY MODE
-----------	---------------

03/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/517,858

Applicant(s)

MOHAMMAD, HASSAN

Examiner

BETHANY BARHAM

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 9-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of Applicant's response and claim amendments filed on 3/21/2008 is acknowledged. The previously submitted abstract (12/14/04) is sufficient. Claims 1 and 9-16 are pending.

Restriction

Newly submitted claims 1 and 9-15 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: they a process of producing claims and the original claims were directed to a product.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1 and 9-15 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claim 16 is rejected.

Due to Applicant's claim amendments the previous rejections of record are hereby withdrawn.

NEW REJECTIONS

Claim Rejections - 35 USC § 102

Art Unit: 1615

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by US 4,767,627 ('627).

The instant claims are drawn to an extruded pharmaceutical product for retention in the stomach comprising an extrudate of a mix of hydratable polymer and active ingredient, the product prepared by the process comprising extruding of the mix of hydratable polymer and active ingredient using an extrusion mould designed to provide an extrudate with a rolled or prefolded configuration or an extrudate which is a hollow tube, and cutting the extrudate to give a plurality of rolled sheets, prefolded sheets or sealed tubes.

- '627 teaches a drug delivery device retained in the stomach comprising a planar figure made from an erodible polymer that may release the drug over a controlled, predictable, and extended time (abstract, claim 1). Figs. 1-6 teach the rolled or folded extrudate which is inserted into a hollow tube for delivery to the stomach, that is large enough and rigid enough that when flat it will not pass out of the stomach (col. 4, lines 8-25).
- Various erodible polymers are taught in the '627 and include cellulose, Eudragits, etc and the drug is mixed or dispersed in the polymer prior to

formation (col. 5, lines 46-col. 6, line 55) and extrusion is taught (col. 5, lines 11) (according to the limitations of claim 16).

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by US 4,758,436 ('436).

The instant claims are drawn to an extruded pharmaceutical product for retention in the stomach comprising an extrudate of a mix of hydratable polymer and active ingredient, the product prepared by the process comprising extruding of the mix of hydratable polymer and active ingredient using an extrusion mould designed to provide an extrudate with a rolled or prefolded configuration or an extrudate which is a hollow tube, and cutting the extrudate to give a plurality of rolled sheets, prefolded sheets or sealed tubes.

- '436 teaches a drug delivery device retained in the stomach comprising a ring figure made from polymers that may release the drug over a controlled, predictable, and extended time (abstract, claim 1). Figs. 1-2 teach the rolled or folded extruded figure can be solid or hollow which is inserted into a hollow tube for delivery to the stomach and that is large enough and rigid enough that when flat it will not pass out of the stomach (col. 4, lines 19-40).
- Various erodible polymers are taught in '436 and include cellulosics, Eudragits, etc and the drug is mixed or dispersed in the polymer prior to formation (col. 7, lines 11-60) and extrusion is taught (col. 4, line 24; col. 6, lines 11) (according to the limitations of claim 16).

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by US 5,439,966 ('966).

The instant claims are drawn to an extruded pharmaceutical product for retention in the stomach comprising an extrudate of a mix of hydratable polymer and active ingredient, the product prepared by the process comprising extruding of the mix of hydratable polymer and active ingredient using an extrusion mould designed to provide an extrudate with a rolled or prefolded configuration or an extrudate which is a hollow tube, and cutting the extrudate to give a plurality of rolled sheets, prefolded sheets or sealed tubes.

- '966 teaches a drug delivery device retained in the stomach comprising a figure made from polymers that may release the drug over a controlled time (col. 1, lines 28-29; col. 7, lines 44-50). '966 teaches that the device can be a sheet, slab, cylinder, or rod that can be hollow and further rolled or folded and inserted into a hollow tube for delivery to the stomach (col. 2, lines 53-58; col. 4, lines 67- col. 5, line 2; col. 5, lines 24-32) and that is large enough and rigid enough that when flat it will not pass out of the stomach (col. 4, lines 19-40).
- Various polymers are taught in '966 and include polyethylene oxide, etc and the drug is mixed or dispersed in the polymer prior to formation (col. 5, lines 56-60) and extrusion is taught (col. 3, line 38-55) (according to the limitations of claim 16).

Cited As Interest

US 5,582,837 is cited as interest as teaching a sustained release oral drug dosage form that comprises a tablet or capsule containing a plurality of particles of a drug dispersed in celluloses and once ingested the tablet or capsule disintegrates and the particles swell and are retained in the stomach (abstract) and extrusion is taught (col. 6, lines 1-5; Examples 10 and 21).

Response to Arguments

Applicant's arguments with respect to claims 1-8 (of which only claim 1 is pending and withdrawn) have been considered but are moot in view of the new grounds of rejection necessitated by applicants' amendments. Newly added claim 16 is directed to an extruded pharmaceutical product that now contains process limitations and requires the extrudate to be of a specific form.

Conclusions

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 1615

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bethany Barham
Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615